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EXAMINER

REDDING, DAVID A

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/768,332

Applicant(s)

YONEKAWA ET AL.

Examiner

David A. Redding

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/16/04; 1/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group II in the reply filed on 11/21/05 is acknowledged. The traversal is on the ground(s) that the groups are not distinct species. This is not found persuasive because the independent claims of each group are considered to be patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 specifies a DNA microarray. However it is unclear if the array includes immobilized DNA material.

Claim Rejections - 35 USC § 102

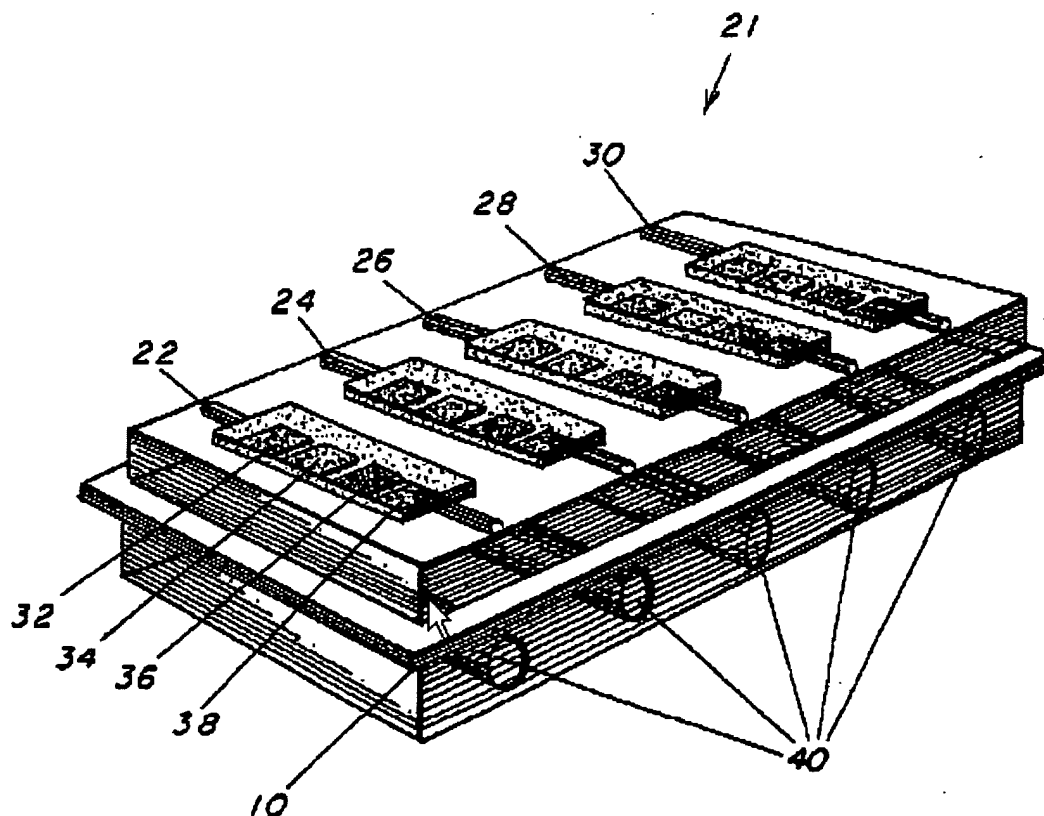
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-14 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,676,904 (Lee et al.).

The Lee et al. patent discloses an apparatus for the fluorescent measurement of a plurality of microarrays. The apparatus is generally disclosed for performing a variety of binding assays including, DNA and RNA (col.1, lines 21-31; col.6, lines 36-51), which involves fluorescent labeling (col.8, lines 15-44). The arrays are formed on a microporous membrane (10) which has nanopores (16) (figures 1 and 2). Different binding agents (12,14), preferably different DNA oligonucleotides probes (col.6, lines 36-40) are immobilized to the membrane in an array format (32,34,36,38; see figure 3). A variety of DNA samples can be contacted with each of the arrays in a fluid manifold (21).



Once the assay reaction has been performed the detection is performed with an apparatus consisting generally of an optical microscope (44) for imaging, which is connected to a video camera (46), video recorder and computer (49).

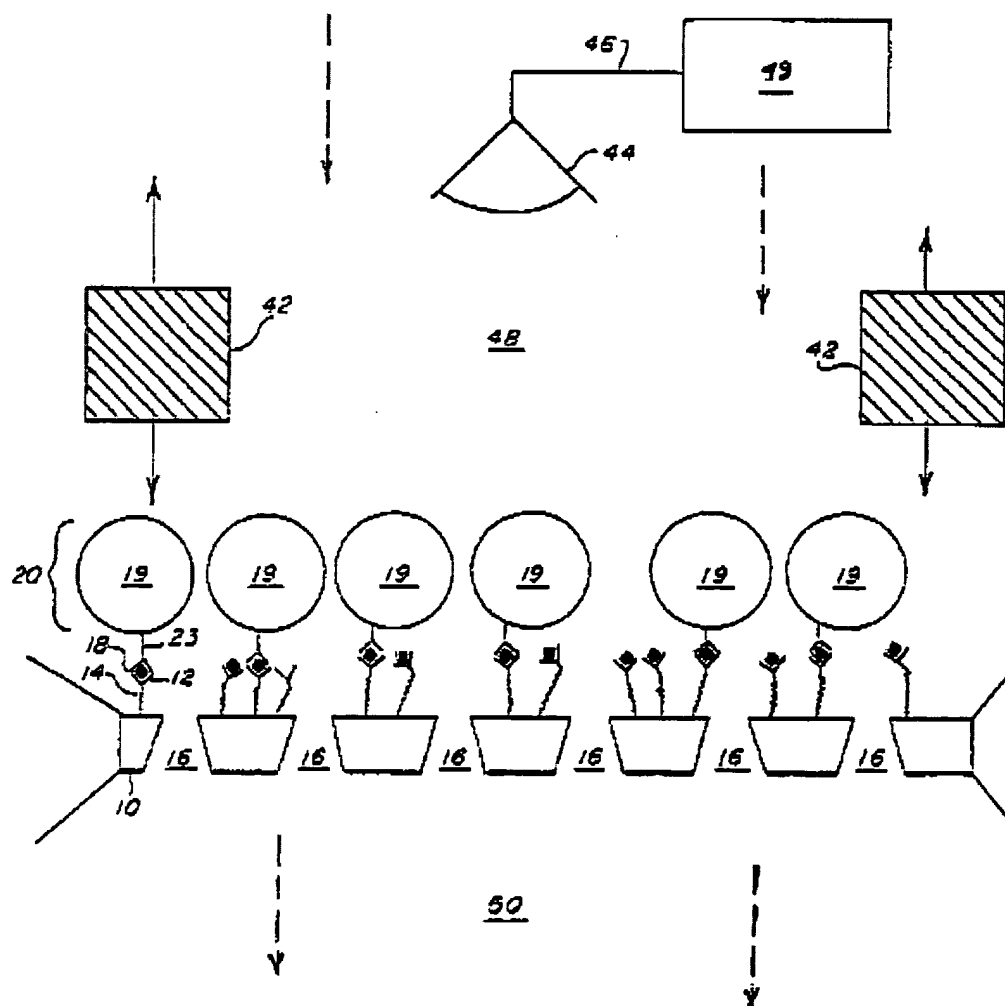


FIG. 4

The apparatus is disclosed as being capable of capturing a digital image from the microscope and analyzing using image analysis algorithms. Further the system is capable of distinguishing reacted and non-reacted sites on the arrays and to monitor

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fluid movement (col.12, lines 11-26; col. 13, lines 5-10). Accordingly, the microporous membrane with the plurality of binding sites is considered to read on the claimed microarray, the fluid transporting section is shown in figure 3, and the computer control and analysis system shown in figure 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

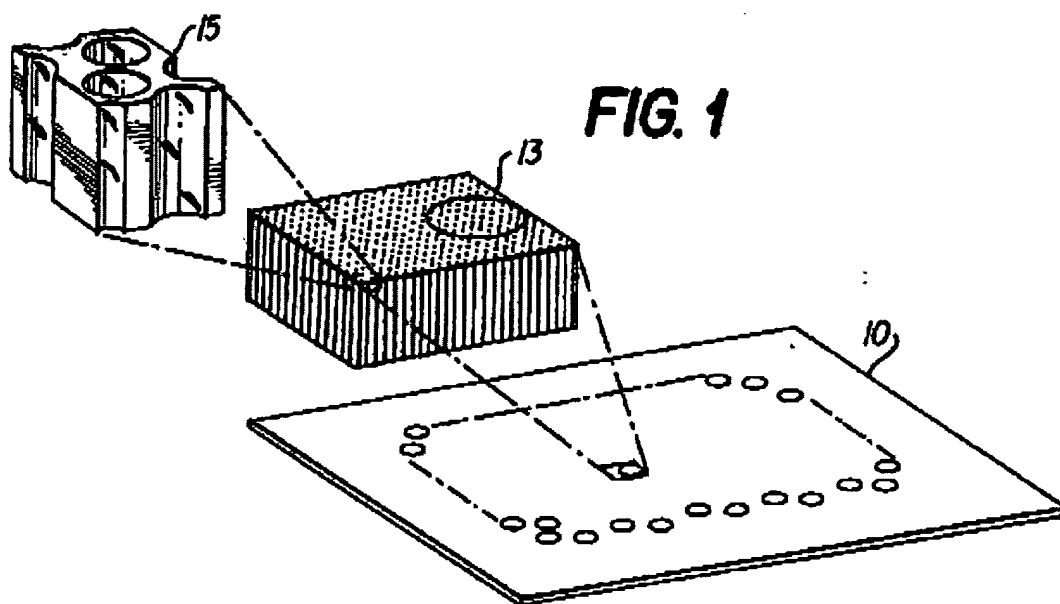
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0137604 (Goodman et al.) in view of USP 6,345,115 (Ramm et al.).

The Goodman et al. patent discloses substantially the claimed invention. Goodman et al. discloses the use of a genosensor device, such as a "FLOW-THRU CHIP" (trademark) which is a microporous substrate comprising a plurality of three-dimensional microarrays which allow for multiple DNA assay

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To be carried out in parallel so that a multiplicity of individual and simultaneous binding reactions occur. Figure 1 below shows the chip having a plurality of microarrays (13) which upon close inspection consist of a plurality of discrete microchannels (15) which are to contain the immobilized oligonucleotide probes (page #1, paragraph 002 thru 008, especially paragraph #004).



The chip is contained within a flow-through cartridge (210) which is considered to be equivalent to the claimed "fluid transporting section". The cartridge (210) is constructed so as to enable real-time hybridization detection (page 3, paragraph #0042 thru paragraph #0044). The DNA Hybridization detection system is shown in figure 2. Besides the cartridge (210) the system is disclosed as :

[0045] The system controller 250, coupled to the test fluid delivery system 220, the detection system 240, and the environmental control system 230, can control and monitor a hybridization assay. The detection system 240 can include microfabricated optical and electronic detection components, film devices, charge-coupled-device arrays, camera systems, and phosphor storage devices that are known in the art. The test fluid delivery system 220, which can be, for example, a fluidics station 800 shown in FIG. 11, includes a pump and one or more valves coupled to buffers and test fluid mixtures that provide a controlled flow of a test fluid mixture to the FTC cartridge 210. In addition, the test fluid delivery system 220 can be further designed to circulate pre-test and post-test cleansing fluids for multiple assay applications. Advantageously, the flow through devices can be reused in the FTC cartridge 210 according to the present invention.

[0046] The system controller 250 can include a microprocessor or computer that is programmed with software, such as Lab-View (available from National Instruments, Austin, Tex.) that can control one or more of the systems described above. With the control system of the present invention, flow rates, buffer selection, temperature, and timing for one or more FTCs can be controlled independently. These components will be described in detail below.

See page 3, paragraph # 0045,0046.

The reference is silent as to an image display, although all computers have displays, or an image processing section which determines the intensity of the optical signal. The US patent to Ramm et al. discloses a system for performing image intensity analysis specifically for DNA microchip hybridization assays (col.2, lines 53 thru 67). The components of the system a computer with software which integrates control, detection and analysis, specifically, quantifying the intensity of the image (col.7, line 45 thru col.8, line 67). Accordingly, it would have been obvious to one skilled in the art to use the computer control, detection and analysis system described in the Ramm et al. patent in

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the system and method disclosed in Goodman et al. in view of the use of the Ramm et al. system for hybridization assays.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The US patents to Rahbar-Dehghan discloses microarrays having channels for immobilization of probes on the inside surface; the publication to Weiner et al. discloses similar microporous arrays with channels; the patents to Beattie, Anderson et al, and Hosoi disclose microarrays on biochips for DNA hybridization assays; and the US publication to Montague et al. discloses a complete fluorescence system for performing DNA hybridization image analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David A. Redding". The signature is fluid and cursive, with a large, stylized "D" and "R".

David A Redding
Primary Examiner
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DAR